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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,887	01/05/2004	Ching-Hsiang Hsu	001409.00008	2087

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WASHINGTON, DC 20001

EXAMINER

BAGGOT, BRENDAN O

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 04/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/750,887

Applicant(s)

HSU ET AL.

Examiner

Brendan O. Baggot

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 29-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/27/05</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Restriction / Election***

1. The Office acknowledges the receipt of Applicant's restriction election, filed 1/5/04 Applicant elects Group III claims 1-28 and ZYMV, without traverse. Claim 1-34 are pending. Claims 29-34 are nonelected. Claims 1-28 is/are examined in the instant application. This restriction is made FINAL.

### ***Specification***

2. The abstract of the disclosure is objected to because "The present invention" is considered legalese. Correction is required. See M.P.E.P. § 608.01(b).

### ***Claim Objections***

3. Claim 15 is objected to because of the following informalities: "an dust mite" is improper claim language. Appropriate correction is required.

### ***Information Disclosure Statement***

4. An initialed and dated copy of Applicant's IDS form 1449 filed 1/5/04 is attached to the instant Office Action.

### ***Drawings***

5. The drawings are acceptable for examination.

### **Claim Rejections - 35 USC § 35 U.S.C. §112, second paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 5, 6, 9, 23 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

In Claims 5, 6, the metes and bounds of "modified" cannot be determined since Applicant has not defined said modified. All subsequent recitations of "modified" are also rejected.

Claims 10, 24 reciting "the plant" lack antecedent basis.

Claims 14, 28 reciting "provided" lack antecedent basis. Does Applicant mean obtained?

Clarification and/or correction are required.

***Claim Rejections - 35 U.S.C. §112, first paragraph***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-6, 19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for ZYMV, does not reasonably provide enablement for a modified plant virus vector. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make

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modifications, practice / make and use the invention commensurate in scope with these claims. While the ordinarily skilled artisan can readily make modifications, Applicant has failed to provide any guidance as to which modifications are required. Accordingly, the claims are not enabled commensurate with the scope claimed.

***Claim Rejections - 35 U.S.C. §103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-4, 7-18, 21-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mason, et al ((PG PUB 0079248 A1, 4/03) and further in view of Hsu et al (International Immunology, 8:1405-1411, 1996). Mason teaches a process for producing a protein comprising the steps of: (a) constructing a plant transformation vector that comprises a DNA sequence operably linked to a plant-specific promoter, transforming a plant cell with the vector, and obtaining the protein from the plant cell (pp. 1-83). Mason further teaches an edible protein (parag. 222), modified plant virus vector (See the title, abstract, and parag.s 287, 288, 296, 365 for example), an ER signal peptide (parag. 47), a 35s promoter (parag. 47), a selectable marker (parag. 109), a process for producing an antigenic composition (See parag. 387 for example), and a potato (parag. 103). Mason does not teach dust mite allergen Der p 5. Hsu

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teaches dust mite allergen, Der p 5 cDNA, expression of Der p 5, and Der p 5 protein (See the abstract; p. 1406, 3<sup>rd</sup> parag.; p. 1406, 5<sup>th</sup> parag., right hand side) and that dust mite allergen causes disease affecting 20% of the population and is an important cause of morbidity and mortality (Hsu, p. 1405).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to substitute the Der p 5 cDNA taught by Hsu for the BeYDV (for example) protein taught by Mason for the purposes of expressing Der P 5 in potato or other edible plant or plant portion to create an edible therapeutic agent. One skilled in the art would have been motivated to generate the claimed invention with a reasonable expectation of success.

10. Claims 1-3, 5-17, 19-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al (Bot. Bull. Acad. Sin. 43: 261-268, 2002) and further in view of Hsu et al (International Immunology, 8:1405-1411, 1996). Lin teaches a ZYMV based system for expressing foreign proteins in cucurbits. ZYMV as a vector to express foreign proteins of interest. (p. 267, last para.) Lin does not teach Der p 5. Hsu teaches dust mite allergen, Der p 5 cDNA, expression of Der p 5, and Der p 5 protein (See the abstract; p. 1406, 3<sup>rd</sup> parag.; p. 1406, 5<sup>th</sup> parag., right hand side) and that dust mite allergen causes disease affecting 20% of the population and is an important cause of morbidity and mortality (Hsu, p. 1405). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made substitute the Der p 5 protein of Hsu for the generic foreign protein in the ZYMV vector expression system of Lin for the purpose of expressing Der p 5 in cucurbits such as

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*Cucurbita pepo* L. var. Zucchini to create an edible therapeutic agent. One skilled in the art would have been motivated to generate the claimed invention with a reasonable expectation of success.


### Remarks

11. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brendan O. Baggot whose telephone number is 571/272-5265. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571/272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

 4/10/06  
Brendan O. Baggot  
Patent Examiner  
Art Unit 1638

 4/10/06  
PHUONG T. BUI  
PRIMARY EXAMINER

bob